HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Refer to: FEI 3002853384

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

April 3, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph W. DeBrouse, Owner
Body Vibes
P.O. Box 878
Louisa, Virginia 23093

Dear Mr. DeBrouse:

On November 10 and 15, 1999, a Food and Drug Administration (FDA) Investigator conducted an inspection and collected information that revealed a serious regulatory problem involving a product made and marketed by your firm known as "Body Vibes System I & II."

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act). The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they offer them for sale. This helps protect the public health by ensuring that new medical devices have been shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your product for sale. The type of information you need to submit in order to obtain this clearance can be obtained by contacting our Division of Small Manufacturers Assistance (DSMA) at 1-(800) 638-2041, or by FAX at (301) 443-8818, and requesting the New Manufacturers Information package. The FDA will evaluate the information you submit and decide if your product may be legally marketed.

Because you do not have clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is misbranded within the meaning of Section 502(o) and adulterated under Section 501(f)(1)(B) of the Act. Your product is misbranded under the Act because it is manufactured in an establishment not duly registered under Section 510, is not included in a list required by Section 510(j), and because information has not been provided to FDA to show that your device is substantially equivalent to other devices that are legally marketed, as required by Section 510(k).

Until your device is determined by FDA to be substantially equivalent, it is classified by statute as a Class III device. As such, your product is adulterated within the meaning of Section 501(f)(1)(B), in that it is a Class III device under Section 513(f) and does not have an approved application for pre-market approval in effect pursuant to Section 515(a), or an approved application for an investigational device exemption under Section 520(g).

Your product is also misbranded within the meaning of Section 502(a), in that the labeling (i.e., the compact disc label (front and back), promotional pamphlet, and literature) represents or suggests that the device is adequate and effective for the diagnosis, treatment, or prevention of diseases or conditions, including, but not limited to, parasites, cancer and diabetes. These representations or suggestions are false and misleading, or otherwise contrary to fact, because the device is not adequate or effective for such purposes. For your information, see the enclosed attachment which describes the labeling claims that cause your product to be misbranded.

Additionally, your product is misbranded within the meaning of Section 502(f)(1), in that the labeling fails to bear adequate directions for use. Adequate directions cannot be written for the diagnosis, treatment, or prevention of diseases or conditions for which the device cannot adequately and effectively treat.

Lastly, your product is misbranded within the meaning of Section 502(f)(1), in that it is a prescription device, which can only be safely used under the supervision of a licensed practitioner and it does not meet the requirements applicable to prescription devices found in Section 801.109 of Title 21 of the Code of Federal Regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure of your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Additionally, Federal agencies are informed about the Warning Letters we issue, so that they may consider this information when awarding government contracts.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, as to the specific steps you have taken to correct the noted violations and to prevent their recurrence, including the timeframe within which the corrections will be completed. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter addresses issues relating to pre-market clearance and the registration and listing of your device, and does not necessarily address other obligations you may have under the law. You may obtain general information regarding FDA's requirements for manufacturers of medical devices by contacting DSMA or through the Internet at http://www.fda.gov.

If you have more specific questions about the content of this letter, please feel free to contact Scott MacIntire, Compliance Officer, at (804) 379-1627, extension 14.

Sincerely,

Roberta F. Wagner
Acting Director, Baltimore District

Attachment